

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 39

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte BARRETT ROLLINS, and
CHARLES STILES

Appeal No. 2001-0869
Application No. 08/453,347

ON BRIEF

Before WILLIAM F. SMITH, SCHEINER, and GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-16, all of the claims remaining. Claims 1-6 are representative and read as follows:

1. A method of suppressing tumor formation in a mammal comprising administering to said mammal tumor killing cells which have been genetically engineered to express JE/monocyte chemoattractant protein-1 when present in the mammal.
2. A method of Claim 1 wherein the tumor killing cells are tumor infiltrating lymphocytes.

3. A method of increasing monocyte mediated tumoricidal activity in a mammal comprising administering to said mammal a therapeutically effective amount of mammalian cells that express JE/monocyte chemoattractant protein-1 when present in the mammal.
4. A method of treating a localized side-effect of malignancy in a mammal comprising locally administering to the mammal a therapeutically effective amount mammalian cells that have been genetically engineered to express JE/monocyte chemoattractant protein-1 when the cells are present in the mammal.
5. The method of Claim 4 wherein the side effect is selected from the group consisting of pleural effusions or ascites.
6. A method of combatting a parasitic infection in a mammal comprising administering to the mammal a therapeutically effective amount of mammalian cells that express JE/monocyte chemoattractant protein-1 when present in the mammal.

The examiner relies on the following references:¹

Marshall, "Gene therapy's growing pains," Science, Vol. 269, pp. 1050-1055 (1995)

Orkin et al. (Orkin), "Report and recommendations of the panel to assess the NIH investment in research on gene therapy," NIH Report (1995)

LaFont et al. (LaFont), "Which gene for which restenosis?," Lancet, Vol. 346, pp. 1442-1443 (1995)

Anderson, "Gene therapy," Scientific American, pp. 124-128 (September 1995)

Blau et al. (Blau), "Gene therapy – a novel form of drug delivery," New England Journal of Medicine, Vol. 333, No. 18, pp. 1204-1207 (1995)

Crystal et al. (Crystal), "Transfer of genes to humans: Early lessons and obstacles to success," Science, Vol. 270, pp. 404-410 (1995)

¹ In the Answer, the examiner states that "[n]o prior art is relied upon by the examiner in the rejection of the claims under appeal." Page 2. In fact, however, the examiner relies on the references listed above as supporting her enablement analysis. See, e.g., page 5 of the Examiner's Answer.

Vieweg et al. (Vieweg), "Considerations for the use of cytokine-secreting tumor cell preparations for cancer treatment," Cancer Investigation, Vol. 13, pp. (1995)

Claims 1-16 stand rejected under 35 U.S.C. § 112, first paragraph, as nonenabled.

We reverse and enter a new ground of rejection under 37 CFR § 1.196(b).

Background

"The JE gene is a platelet-derived growth factor (PDGF)-inducible 'competence' or 'early response gene' first identified in mouse 3T3 cells. . . . [T]he murine JE gene encodes a secreted glycoprotein with cytokine-like properties. The human homolog of murine JE has been cloned, and the predicted amino acid sequence of its protein is identical to that of a monocyte chemoattractant, MCP-1." Specification, page 4 (reference citations omitted). "The JE/MCP-1 protein is structurally related to the members of a large, recently identified family of low molecular weight secreted proteins that appear to be involved in the inflammatory response." Id., page 5. "Both natural and recombinant JE/MCP-1 are potent chemoattractants for human monocytes in vitro." Id.

"[E]xpression of the JE gene in malignant cells suppresses their ability to form tumors in vivo. This apparent phenotypic reversion requires interaction with host factors in vivo, since expression of JE/MCP-1 does not alter the transformed character of these cells in vitro. Furthermore, . . . JE/MCP-1-expressing cells exert their effect in trans [as shown] by their ability to suppress tumor formation when co-injected with JE/MCP-1-non-expressing tumor cells." Id., page 6.

The specification discloses that JE/MCP-1 can be administered to suppress tumor formation in vivo. See page 2. “The protein can be administered alone or as an adjuvant to surgery.” Id. Alternatively, “tumor killing cells, such as tumor infiltrating lymphocytes (TIL cells) are genetically engineered to express the JE/MCP-1 protein. The engineered cells therefore can be administered to a vertebrate to provide a synergistic local tumor cell killing.” Id., pages 2-3. See also pages 13-16.

The specification also discloses that JE/MCP-1 can be administered to “treat localized complications of malignancy.” See page 2. Finally, JE/MCP-1 can be used for “combatting a parasitic infection in a vertebrate animal by administering to that vertebrate an effective amount of JE/MCP-1.” Id., page 3.

Discussion

The claims are directed to various methods of treatment comprising administering cells that express JE/MCP-1. Claims 1 and 3 are directed to a method of treating cancer (or, as recited in the claims, a “method of suppressing tumor formation” and a “method of increasing monocyte mediated tumoricidal activity,” respectively). Claim 4 is directed to a “method of treating a localized side-effect of malignancy” by “locally administering” cells that express JE/MCP-1. Claim 6 is directed to a “method of combatting a parasitic infection” by administering cells that express JE/MCP-1. The rest of the claims are dependent on one of claims 1, 3, 4, or 6.

The examiner rejected all of the claims as nonenabled, on the basis that “sufficient guidance as to routes of delivery, delivery vectors, dosage amounts

and dosage frequency is not provided so that the artisan can make and use the invention with a reasonable expectation of success without an undue amount of experimentation.” Examiner’s Answer, page 3.

The examiner’s enablement analysis considered several of the Wands factors. See the Examiner’s Answer, pages 3-8. In particular, the examiner found that

- the nature of the invention was “within the realm of gene therapy,” id., page 4;
- “[a]t the time of filing, the art considered gene therapy as unpredictable without an undue amount of experimentation,” id.;
- contemporaneous references showed that much work remained to be done before gene therapy would be clinically applicable, id., pages 5-6;
- “[t]he specification does not teach routes of delivery, vectors, promoters, dosage amounts or dosage frequencies which in combination would guide the artisan to suppress tumor formation, attract monocytes, treat localized side-effects of malignancy or treat parasitic infections,” id., page 6; and
- the animal model used in the specification’s examples “is not seen as being correlatable to [the] claimed invention,” because the model animals did not have preexisting tumors; id., pages 7-8.

The examiner concluded that “the specification does not provide a sufficient guidance to overcome the art recognized unpredictabilities and lack of teachings. Thus, without further guidance from the specification, the claimed methods would not have been enabled at the time of the instant invention because the skilled artisan would have needed to engage [in] an undue amount of experimentation.” Examiner’s Answer, page 8.

Appellants argue that “[t]here is no valid reason why gene therapy inventions should undergo a different or stricter standard of enablement than any other therapy.” Appeal Brief, page 9. Appellants cite Orkin as disclosing that “[b]y 1995, more than one hundred federally approved clinical trials were underway on gene therapy protocols.” Appeal Brief, page 14. Since, Appellants argue, “the requirements for FDA approval are in fact more stringent than requirements for enablement,” the federally approved clinical trials provide evidence that the claimed methods should not be held to be nonenabled simply because they involve gene therapy. See the Appeal Brief, page 15.

Appellants also argue that the references cited by the examiner do not provide evidence of nonenablement, because the problems addressed in those references concerned the clinical success and commercial viability of gene therapy techniques, considerations that go beyond what is required for enablement. See the Appeal Brief, pages 17-21. Finally, Appellants argue that their position is supported by In re Brana, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995). See the Appeal Brief, pages 30-34.

“When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement. If the PTO meets this burden, the burden then shifts to the

applicant to provide suitable proofs indicating that the specification is indeed enabling.” In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

“[E]nablement requires that the specification teach those in the art to make and use the invention without ‘undue experimentation.’ That some experimentation may be required is not fatal; the issue is whether the amount of experimentation required is ‘undue.’” In re Vaeck, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991) (citation omitted, emphasis in original). “Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations.” In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Those considerations, see id., are well known and need not be repeated here.

In this case, we agree with appellants that the examiner has not shown that undue experimentation would have been required to practice the claimed method. The examiner’s concerns, and the evidence cited in support of the rejection, are directed to sources of unpredictability and experimentation involved in gene therapy in general, rather than the claimed method in particular. Granted, the examiner’s references show that (at least as of 1995) gene therapy techniques, as a group, required further experimentation before they would be ready for clinical application. This showing, however, is not enough to support a rejection of the instant claims for nonenablement.

First, a therapeutic method need not be ready for clinical application in order to be enabled. See In re Brana, 51 F.3d 1560, 1567, 34 USPQ2d 1436, 1442 (Fed. Cir. 1995): “Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans.”² The Brana court noted that the CCPA has held that “proof of an alleged pharmaceutical property for a compound by statistically significant tests with standard experimental animals is sufficient to establish utility.” Id. at 1567, 34 USPQ2d at 1442 (citing In re Krimmel, 292 F.2d 948, 953, 130 USPQ 215, 219 (CCPA 1961)). The instant specification provides an example of tumor suppression in an animal model. See pages 9-10 and Figures 2A and 2B.

Again, at the risk of being repetitive, evidence that a claimed method was not ready for clinical application is not enough to show nonenablement. What is needed is evidence or sound scientific reasoning that undue experimentation would have been required to carry out the claimed methods. The claims are variously directed to methods of “suppressing tumor formation,” “increasing monocyte mediated tumoricidal activity,” “treating a localized side-effect of malignancy,” or “combatting a parasitic infection,” and therefore imply some degree of therapeutically beneficial effect. That standard, however, is more lenient than the standards by which clinical trials are judged. See, e.g., Brana,

² Although the Brana court referred to “usefulness,” the rejection on appeal was based on 35 U.S.C. § 112, first paragraph. See 51 F.3d at 1564, 34 USPQ2d at 1439.

51 F.3d at 1568, 34 USPQ2d at 1442 (“On the basis of animal studies, and controlled testing in a limited number of humans (referred to as Phase I testing), the Food and Drug Administration may authorize Phase II clinical trials. . . . Authorization for a Phase II study means that the drug may be administered to a larger number of humans, but still under strictly supervised conditions. The purpose of the Phase II study is to determine primarily the safety of the drug . . . as well as its potential efficacy under different dosage regimens.”).

In this case, we have no fact-based explanation from the examiner focused on the claimed method, as opposed to gene therapy as a general field, to establish that the instant claims are nonenabled. In addition, it is well-established that the amount of experimentation that is considered “undue” varies from one field to another. See, e.g., Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (factors relating to undue experimentation include quantity of experimentation necessary, nature of the invention, and relative skill of those in the art). In this case, the evidence shows that “[m]ore than 100 clinical protocols for gene therapy ha[d] been reviewed and approved” by the NIH as of 1995. Orkin, page 12. See also Anderson, page 128, and Blau, page 1206 (summarizing clinical trials approved as of 1995).

Orkin states that these protocols were not intended to establish efficacy (page 13), but these references show that those of skill in the art of gene therapy regularly applied therapeutic techniques to human patients, despite the problems remaining to be overcome before the techniques could be widely applied clinically. Thus, the gene therapy protocols cited by Orkin, Anderson, and Blau

provide evidence that those practicing gene therapy techniques would not have considered the obstacles cited by the examiner to be a barrier to applying gene therapy in human patients, and therefore, that those obstacles would not have been considered to be a source of undue experimentation in this field. There is no evidence in the record that the claimed gene therapy methods would have been likely to involve excessive experimentation when considered relative to other methods practiced in the field of gene therapy.

Thus, we conclude that the examiner has not shown that the amount of experimentation required to practice the instant claims would have been considered undue by those skilled in the art of gene therapy. The rejection for nonenablement is reversed.

New Ground of Rejection

Under the provisions of 37 CFR § 1.196(b), we make the following new ground of rejection: claims 1-3 and 7-16 are rejected under the equitable doctrine of interference estoppel.

The doctrine of interference estoppel “bar[s] the assertion of claims for inventions that are patentably indistinct from those in an interference that the applicant had lost.” In re Deckler, 977 F.2d 1449, 1452, 24 USPQ2d 1448, 1449 (Fed. Cir. 1992). See also 37 CFR § 1.658(c).³

³ “A judgment in an interference settles all issues which (1) were raised and decided in the interference, (2) could have been properly raised and decided in the interference by a motion under § 1.633 (a) through (d) and (f) through (j) or § 1.634, and (3) could have been properly raised and decided in an additional interference with a motion under § 1.633(e). A losing party who could have properly moved, but failed to move, under § 1.633 or 1.634, shall be estopped to take ex parte or inter partes action in the Patent and Trademark Office after the interference which is inconsistent with that party’s failure to properly move, except that a losing party shall not

Deckler arose out of “an interference proceeding . . . between Deckler and Grataloup, . . . [in which] the Board awarded priority of invention to Grataloup.” Id. at 1451, 24 USPQ2d at 1448. Deckler’s application was returned to ex parte prosecution, rejected on various grounds, and appealed. See id. “The Board affirmed the examiner’s rejection of claims 1 through 3 and 7 on the ground that the decision in the interference precluded Deckler from allowance of those claims, because they define the same invention as the interference count.” Id. Deckler appealed to the Federal Circuit, and the court affirmed, holding that

[t]he Board’s decision that the interference judgment bars Deckler from obtaining a patent for claims that are patentably indistinguishable from the claim on which Deckler lost the interference constituted a permissible application of settled principles of res judicata and collateral estoppel. Under those principles, a judgment in an action precludes relitigation of claims or issues that were or could have been raised in that proceeding.

Id. at 1452, 24 USPQ2d at 1449. The court concluded that

[t]he interference judgment conclusively determined that, as between Deckler and Grataloup, Grataloup was entitled to claim the patentable subject matter defined in the interference count. It is therefore proper, and consistent with the policies of finality and repose embodied in the doctrines of res judicata and collateral estoppel, to use that judgment as a basis for rejection of claims to the same patentable invention.

Id.

In this case, interference 103,998 involved Appellants’ U.S. Patent 5,179,078 and application 07/330,446, filed by Yoshimura et al. The sole count in the interference read as follows: “A method of treating neoplasms or tumors in

be estopped with respect to any claims which correspond, or properly could have corresponded, to a count as to which that party was awarded a favorable judgment.” 37 CFR § 1.658(c).

humans comprising administering an effective amount of a purified human JE/MCP-1 protein.” See Paper No. 1 in the ‘998 interference, mailed October 9, 1997.

Claims 1, 2, 5, and 6 of Appellants’ ‘078 patent were designated as corresponding to the count. See id. Those claims read as follows:

1. A method of suppressing tumor formation in a mammal comprising administering to said mammal a therapeutically effective [sic] amount of JE/Monocyte Chemoattractant Protein-1 (JE/MCP-1).
2. A method of increasing a monocyte mediated tumoricidal activity in a mammal comprising administering to said mammal an effective amount of JE/Monocyte Chemoattractant Protein-1.
5. A method of suppressing tumor formation in a mammal comprising administering to said mammal tumor killing cells which express JE/Monocyte Chemoattractant Protein-1.
6. A method of claim 5, wherein the tumor killing cells are tumor infiltrating lymphocytes.

Appellants did not move to have any of these claims designated as not corresponding to the count. The interference was terminated after Appellants “concede[d] priority of invention for the count of the . . . interference to Senior Party Yoshimura et al.” Paper No. 25, filed Sept. 18, 1998. This concession was “treated as a request for entry of an adverse judgment as to all claims which correspond to the count,” Paper No. 27, mailed Nov. 24, 1998, and Appellants were adjudged “not entitled to a patent containing claims 1, 2, 5 and 6 corresponding to the count.” Id.

Instant claims 1 and 2 read as follows:

1. A method of suppressing tumor formation in a mammal comprising administering to said mammal tumor killing cells which

have been genetically engineered to express JE/monocyte chemoattractant protein-1 when present in the mammal.

2. A method of Claim 1, wherein the tumor killing cells are tumor infiltrating lymphocytes.

As can be seen, the only difference between instant claims 1 and 2 and claims 5 and 6 of the '078 patent, respectively, is that the instant claims expressly require that the administered cells "have been genetically engineered to express JE/monocyte chemoattractant protein-1 when present in the mammal," while claims 5 and 6 simply state that the cells "express JE/Monocyte Chemoattractant Protein-1." We conclude that this difference in semantics does not patentably distinguish the instant claims from the claims that Appellants lost in the earlier interference.

Patent claims are construed in light of the specification. See, e.g., Renishaw plc v. Marposs Societa per Azioni, 158 F.3d 1243, 1248, 48 USPQ2d 1117, 1120 (Fed. Cir. 1998). ("[A] claim must be read in view of the specification of which it is a part."). The specification of the '078 patent provides the following relevant disclosure:

- "In a further embodiment tumor killing cells, such as tumor infiltrating lymphocytes (TIL cells) are genetically engineered to express the JE/MCP-1 protein. The engineered cells therefore can be administered to a vertebrate to provide a synergistic local tumor cell killing." Col. 1, line 66 to col. 2, line 3.
- "The JE gene . . . [was] first identified in mouse 3T3 cells." Col. 2, lines 51-53.
- "The human homolog of murine JE has been cloned," col. 2, lines 60-61, although the specification does not disclose what cell line or type was the source of the human JE gene.

- Cells expressing JE/MCP-1 were created by transforming cells with a vector comprising murine or human JE cDNA. No detectable JE/MCP-1 was produced in cells transformed with the expression vector alone, but “[c]onsiderable JE/MCP-1 protein was secreted by cell lines transfected with murine JE cDNA in the sense orientation . . . and human JE cDNA.” Col. 3, line 52, to col. 4, line 17.
- “Transfected Chinese Hamster Ovary cell lines” containing “JE cDNA” did not form tumors when injected into animals. See Table 1 (col. 4, line 55, to col. 5, line 13).
- Co-injection of JE/MCP-1-expressing cells together with untransformed, tumor-forming cells resulted in suppression of tumor formation; the JE/MCP-1-expressing cells (cell lines 10A-10, hJEC-10, and hJEC-100) were transfected with murine or human JE/MCP-1 cDNA. Col. 5, lines 33-59 and Table 1.
- For treatment of cancer, JE/MCP-1 protein can be administered directly (col. 6, line 67, to col. 8, line 3), or “[a]lternatively, tumor killing cells, such as tumor infiltrating lymphocytes (TIL cells) could be genetically engineered to express the JE/MCP-1 protein. Tumor killing cells engineered in this way can provide synergistic local tumor cell killing. The tumor killing cells could be engineered in vitro and administered to the vertebrate or the tumor killing cells could be engineered in vivo into the vertebrate’s own supply of tumor killing cells using methods which are known in the art.” Col. 8, lines 4-12.

Thus, the only JE/MCP-1-expressing cells described in the ‘078 patent are cells that have been genetically engineered to express JE/MCP-1. When read in light of the ‘078 patent’s specification, the patent’s claims 5 and 6 must be interpreted to be directed to a method of suppressing tumor formation by administering tumor killing cells that have been genetically engineered to express JE/MCP-1. Thus, instant claims 1 and 2 are directed to the same method as defined by the patent’s claims, properly construed, and they are not patentably distinguished from the claims that Appellants lost in the ‘998 interference.

Instant claims 3 and 7-16 are also not patentably distinguished from the method corresponding to the lost count of the '998 interference. Claim 3 is directed to a

method of increasing monocyte mediated tumoricidal activity in a mammal comprising administering to said mammal a therapeutically effective amount of mammalian cells that express JE/monocyte chemoattractant protein-1 when present in the mammal.

Thus, claim 3 differs from the '078 patent's claim 5 in two respects. First, the patent claim is limited to "tumor killing cells," while claim 3 encompasses any mammalian cell. Second, the claims differ in their preambles.⁴

These differences do not patentably distinguish claim 3 from the subject matter of the '078 patent's claim 5. While claim 3 is broader than the patent's claim with respect to the types of cells that can be used in the claimed method, "a later genus claim limitation is anticipated by, and therefore not patentably distinct from, an earlier species claim." Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 971, 58 USPQ2d 1869, 1880 (Fed. Cir. 2001).

Nor does the difference in preambles patentably distinguish the claims. The instant specification makes clear that the antitumor activity of JE/MCP-1 is mediated by monocytes. See page 2, lines 15-17 ("The [tumor] suppressive effect of JE/MCP-1 depends on the induction of the vertebrate's immune response, specifically the response of monocytes."). Thus, whether the claimed method is characterized as "suppressing tumor formation" or "increasing

⁴ The claims also differ in that claim 3 recites administering a "therapeutically effective amount" but this difference does not distinguish the claims, since it is implied in the patent's claim 5: in

monocyte mediated tumoricidal activity,” the method is the same; the preamble does not imply any difference in the patient treated or in the method’s manipulative steps, and therefore does not change the scope of the claim. Cf. Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1372, 58 USPQ2d 1508, 1513 (Fed. Cir. 2001) (Preamble language reciting “a method for treating a cancer patient to effect regression of a taxol-sensitive tumor, said method being associated with reduced hematologic toxicity” was “only a statement of purpose and intended result. The expression does not result in a manipulative difference in the steps of the claim.”).

Claims 7-16 depend from claims 1 or 3 and add limitations on the form of the JE expressed by the cells.⁵ However, in every case, the claimed method is based on the monocyte chemoattractant activity of naturally occurring JE/MCP-1. Thus, even in claims that recite a “mutation” in the naturally occurring sequence, or a “replacement, insertion or deletion of one or more amino acids,” the claims implicitly require that the protein expressed in the genetically engineered cells retains the same monocyte chemoattractant activity of wild-type JE/MCP-1. Thus, the limitations of claims 7-16 do not patentably distinguish these claims from the claims corresponding to the count lost in the ‘998 interference.

order to be a “method of suppressing tumor formation,” the claimed method would necessarily require administering a therapeutically effective amount of JE/MCP-1-expressing cells.

⁵ For example, claim 7 is directed to “[t]he method of claim 1 wherein the JE/monocyte chemoattractant protein-1 comprises an amino acid sequence from about amino acid #30 to amino acid #99 of human MCP-1, a biologically active fragment or mutation thereof,” and claim 9 adds the further limitation that “the mutation is characterized by the replacement, insertion or deletion of one or more amino acids of the amino acid sequence from about amino acid #30 to amino acid #99 of human MCP-1.”

Thus, claims 1-3 and 7-16 are directed to subject matter that is not patentably distinguished from the claims corresponding to the count of the '998 interference, which Appellants lost. The decision in the interference therefore precludes Appellants from allowance of these claims.

In an earlier communication from this board, Appellants were advised of the potential interference estoppel issue and were ordered to explain why an estoppel does not exist under Rule 658(c) and why the claims are not unpatentable under the principles of In re Deckler. See Paper No. 34, mailed Oct. 29, 2002.

Appellants responded that the claims involved in the '998 interference

are all directed to methods involving administration of JE/MCP-1 protein or cells expressing JE/MCP-1 protein. Thus, the subject matter of the interference is derived from the discovery of the purified protein, its source and its administration. In contrast, claims 1, 3-5 and 7-13 of the present application are all directed to methods involving administration of cells which are genetically engineered to express JE/MCP-1 protein. This discovery is derived from, and enabled by, the isolation of the gene, or DNA, that expresses the protein. This is more closely related to the subject matter of Interference 103,884, to which Appellants were awarded priority. Briefly, Yoshimura et al. were awarded priority to the protein and methods of using the protein (either in pure form or as secreted by a native cell). Rollins et al. (Appellants) were awarded priority to the DNA. Since the manufacture of genetically engineered cells for use in treating patients requires the invention of the DNA, not the protein, these claims are not properly rejected under the doctrine of preclusion or precluded pursuant to 37 CFR § 1.658(c).

Paper No. 38, filed Dec. 30, 2002.

This argument is not persuasive. The claims involved in the '998 interference were not limited to treatment methods comprising administering the

JE/MCP-1 protein itself or cells that naturally express JE/MCP-1. As discussed above, Appellants' '078 patent does not describe methods of administering cells that naturally express JE/MCP-1. Therefore, the '078 patent's claims 5 and 6 are most reasonably construed as directed to administration of cells that have been genetically engineered to express JE/MCP-1, such as the cells described in the '078 patent at, e.g., col. 6, line 67, to col. 8, line 3.

The '884 interference involved claims 1-5 of Appellants' Patent 5,212,073. Those claims are directed to DNA encoding JE/MCP-1 (claim 1), a vector comprising such DNA (claim 2), a mammalian or bacterial cell transformed with such a vector (claims 4 and 5), and a method of making JE/MCP-1 (claim 3). The count in the '884 interference read as follows: "An isolated and purified DNA molecular [sic] encoding human JE protein or MCP-1 protein, said protein possessing monocyte chemoattractant activity." See Paper No. 1 in the '884 interference. Thus, neither the count nor any of Appellants' involved claims in the '884 interference were directed to a method of treatment. Appellants' favorable judgment in the '884 interference thus does not preclude rejection of the present claims on the basis of the adverse judgment in the '998 interference.

To the extent that Appellants' position is that the present claims should be considered to correspond to the count of the '884 interference (which Appellants won), we disagree. As discussed above, claims 5 and 6 of Appellants' '078 patent should be construed as directed to methods of treatment using genetically engineered cells. Thus, it appears that Appellants could have moved to have these claims designated as not corresponding to the count of the '998 interference

and designated as corresponding to the count of the '884 interference.

Appellants, however, did not do so and are now precluded from allowance of claims that are not patentably distinct from the claims corresponding to the lost count. See In re Deckler, 977 F.2d at 1452, 24 USPQ2d at 1449:

The Board's decision that the interference judgment bars Deckler from obtaining a patent for claims that are patentably indistinguishable from the claim on which Deckler lost the interference constituted a permissible application of settled principles of res judicata and collateral estoppel. Under those principles, a judgment in an action precludes relitigation of claims or issues that were or could have been raised in that proceeding."

(Emphasis added.)

Summary

We reverse the rejection for nonenablement and enter a new ground of rejection of claims 1-3 and 7-16. Thus, claims 4-6 are not subject to any pending rejection.

This decision contains a new ground of rejection pursuant to 37 CFR § 1.196(b). 37 CFR § 1.196(b) provides, "[a] new ground of rejection shall not be considered final for purposes of judicial review."

37 CFR § 1.196(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of proceedings (37 CFR § 1.197(c) as to the rejected claims:

(1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application will be remanded to the examiner

(2) Request that the application be reheard under
§ 1.197(b) by the Board of Patent Appeals and
Interferences upon the same record

No time period for taking any subsequent action in connection with this
appeal may be extended under 37 CFR § 1.136(a).

REVERSED; 37 CFR § 1.196(b)

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Administrative Patent Judge)	
)	
)	
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